

III. REMARKS

Claims 2, 6 to 8, 12 to 14, 19 to 21, 24 to 26, and 32 to 38 are pending. Claims 1, 3-5, 9-11, 15-18, 22, 23, 29-31, and 39-59 were withdrawn by the Examiner pursuant to 37 C.F.R. § 1.142(b) as allegedly being drawn to non-elected inventions. Applicants previously traversed the restriction requirement in a Response to Restriction Requirement dated April 20, 2007, however, in order to facilitate prosecution, Applicants have canceled claims 1, 3-5, 9-11, 15-18, 22, 23, 27-31, and 39-59 without prejudice to, or disclaimer of, the underlying subject matter. Claims 2, 7, 12, 19, 24 and 26 have been amended. Support for the claim amendments and the new claims may be found in the specification and claims as originally filed. *See, for example*, page 3, line 17 to page 6, line 13. No new matter is added by way of these amendments.

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. Applicants respectfully reiterate that no serious burden would result by the search and examination of the entire application.

Priority

The Examiner has requested that Applicants disclose the sequence identifiers in the priority applications which are identical to SEQ ID NO: 5272 of the instant application. Office Action at page 3. A sequence identical to SEQ ID NO: 5272 of the instant application was first disclosed as SEQ ID NO: 22273 in U.S. Application No. 60/139,932, filed June 21, 1999. A sequence identical to SEQ ID NO: 5272 of the instant application was also disclosed as SEQ ID NO: 42735 in U.S. Application No. 60/143,994, filed July 15, 1999, and as SEQ ID NO: 9911 in U.S. Application No. 60/155,422, filed September 23, 1999.

Objections to the Specification:

The Examiner objected to the disclosure because it allegedly contains embedded hyperlinks. Office Action at page 4. The specification is amended to delete the hyperlinks. Applicants respectfully request withdrawal of the objections to the specification.

Rejections under 35 U.S.C. § 112, second paragraph:

Claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the following reasons:

- Claims 2, 6 to 8, and 12 to 14 for containing the phrase “having the”. Office Action at pages 4, 5. Claims 2, 6 to 8, and 12 to 14 have been amended to replace the phrase “having the” with the phrase “comprising the”.
- Claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 for containing the phrase “complement thereof”. Office Action at pages 4, 5. Claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 have been amended to recite “the complement thereof”, as suggested by the Examiner.
- Claims 7 and 8 for containing the term “sufficient”. Office Action at page 5. The Examiner states that the term “sufficient” is not defined in the claim. Applicants respectfully submit that the Examiner is incorrect. Claim 7 clearly recites that stability should be sufficient “to remain annealed to one another under at least low stringency conditions of washing with a salt solution having a concentration of about 2.0 X sodium chloride/sodium citrate (SSC) at 50°C”. In other words, one of ordinary skill in the art would be able to interpret the metes and bounds of the claim so as to understand how to avoid infringement. Therefore, a

rejection of the claim under 35 U.S.C. § 112, second paragraph, is not appropriate. *See*, M.P.E.P. § 2173.02; *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

- Claims 27, 28, and 32 to 38 for containing the term “between about”. Office Action at page 6. The Examiner cites *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991) as support. However in *Amgen*, the court held that the term “at least about” was invalid for indefiniteness *where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about"*. *Amgen*, 927 F.2d at 1218; M.P.E.P. § 2173.05(b)(A), emphasis added. M.P.E.P. § 2173.05(b)(A) makes clear that the term “about” is definite. *Ex parte Eastwood*, 163 U.S.P.Q. 316 (Bd. App. 1968); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Because one of ordinary skill in the art, in view of the status of the art, would be reasonably apprised of the scope of the invention, the claims are not indefinite. M.P.E.P. § 2173.05(b).
- Claim 28, for allegedly containing broader and narrower ranges. Office Action at pages 6, 7. Applicants respectfully submit that the Examiner has misinterpreted the ranges in claim 28. Claim 28 is directed to the oligonucleotide nucleic acid molecule of claim 27, comprising in the range of 18 to 50 bases, wherein from 18 to 25 of *those* bases are identical or complementary to an 18-25 bp segment of sequences from a fragment of SEQ ID NO: 5272. In other words, the 18 to 25 stretch of bases further defines the 18 to 50 bases. In other words, the metes and bounds of Claim 28 are clear and the claims is not indefinite.

In conclusion Applicants respectfully submits that the pending claims are fully in compliance with the requirements of 35 U.S.C. § 112, second paragraph, and respectfully request withdrawal of these rejections.

Rejection under 35 U.S.C. § 101:

Claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 were rejected under 35 U.S.C. § 101 as allegedly lacking “a credible, substantial, specific or well-established utility.” Office Action at page 7. Applicants respectfully traverse.

The Examiner admits that the specification discloses many uses for the claimed invention. The Examiner states that the claimed nucleic acids may be used “as markers and probes; to identify and obtain nucleic acid homologues; in microarrays as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein.” *Id.* at page 10. However, the Examiner appears to consider none of these utilities specific to the polynucleotides claimed.

One use of the elected SEQ ID NO: 5272 can be shown by a BLASTN analysis. A BLASTN analysis is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. *See* specification page 13, lines 15 to 19. One result from a BLASTN analysis of the claimed SEQ ID NO: 5272 is shown below, and references for the BLASTN results are provided in the IDS submitted herewith. As these results show, the claimed nucleotide sequence shows 97 percent identity to a nucleic acid sequence involved in the metabolic pathway from carbohydrates to seed oil in *Arabidopsis thaliana*.

gb|BE524135.1| **U** M46D1STM Arabidopsis developing seed Arabidopsis thaliana
cDNA
clone M46D1 5', mRNA sequence.
Length=402

Score = 544 bits (602), Expect = 1e-150
Identities = 314/321 (97%), Gaps = 1/321 (0%)
Strand=Plus/Minus

This sequence was obtained by White, J.A., Todd, J., Newman, T., Focks, N., Girke, T., Martinez de Ilarduya, O., Jaworski, J.G., Ohlrogge, J. and Benning, C. and disclosed in a scientific paper entitled "A new set of Arabidopsis expressed sequence tags from developing seed... The metabolic pathway from carbohydrates to seed oil", published in Plant Physiol. 124 (4), 1582-1594 (2000). All information above is readily available from conducting the BLASTN analysis of SEQ ID NO: 5272 through the National Center of Biotechnology Information (NCBI) website.

The specification discloses, for example, that the nucleic acid molecule encodes an *Arabidopsis thaliana* protein. High homology to an *Arabidopsis thaliana* protein is one of the embodiments of the invention. Specification at page 15, line 5 to page 15, line 20. In other words, SEQ ID NO: 5272 (as one example) has utilities specific to it and not generally applicable to any nucleic acid. For instance, SEQ ID NO: 5272 can be used to isolate genes, map genes, and determine gene function associated with carbohydrate metabolism in *Arabidopsis thaliana*. These utilities are credible, substantial, and well-established; they are neither vague nor

impractical. The Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

The utilities disclosed in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). As the Examiner is aware, “a ‘rigorous correlation’ need not be shown in order to establish practical utility; ‘reasonable correlation’ is sufficient.” *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. “An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof.” M.P.E.P. § 2107.03, at page 2100-43. The BLASTN analysis provides such a reasonable correlation through sequence identity: a 97 percent identity to a nucleic acid sequence associated with carbohydrate metabolism in *Arabidopsis thaliana* is a reasonable correlation.

In conclusion, because the Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so with sufficient specificity and reasonable correlation in the present application, the rejection under 35 U.S.C. § 101 is incorrect and the Applicants respectfully request its withdrawal.

Rejection under 35 U.S.C. § 112, first paragraph (Enablement):

Claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Office Action at

page 13. The Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101.

Rejection under 35 U.S.C. § 112, first paragraph (Written Description):

Claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 were also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action at page 14. The Applicants respectfully traverse.

The Examiner argues that “the claims define the nucleic acids in terms of their structure, but do not define the nucleic acids in terms of their functional properties.” *Id.* at page 15. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. For example, Applicants have disclosed a common structural feature, the nucleotide sequence of SEQ ID NO: 5272. Moreover, it distinguishes the members of the claimed genera from non-members. In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences.

The Examiner further states that “the specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.” Office Action at

page 16. Applicants assert that the specification provides an adequate description of the claimed invention because it demonstrates to one skilled in the art that the Applicants were in possession of the claimed genera of nucleic acid molecules when the application was filed. The Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence, of SEQ ID NO: 5272. Nucleic acid molecules falling within the scope of claims 2, 6 to 8, 12 to 14, 19 to 21, 27, 28, and 32 to 38 are readily identifiable and one of ordinary skill in the art can readily identify whether a particular sequence meets the claimed characteristics or not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art, as of the filing date sought, that the Applicants were in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q. 2d 1111, 1117 (Fed. Cir. 1991). An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); M.P.E.P. § 2163.02. In light of the disclosure made by the Applicants in the specification one of ordinary skill in the art at the time the application was filed would have readily recognized that the Applicants were in possession of the invention as claimed. The Examiner has offered no evidence to demonstrate why one of ordinary skill in

the art would reasonably doubt that the invention has not been adequately described in the present disclosure.

In conclusion, the Applicants respectfully submit that the rejections under 35 U.S.C. § 112, first paragraph, are improper and the Applicants respectfully request reconsideration and withdrawal of these rejections.

Rejections under 35 U.S.C. § 102:

Claims 2, 6 to 8, 27 and 28 were rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by GenBank Accession No. AP000604. Office Action at page 19. Applicants respectfully traverse this rejection.

“It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1369, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Further, “an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.” *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). The Examiner has applied an untenable interpretation of the claims to cover sequences that are complementary to SEQ ID NO: 5272 merely at a particular segment of SEQ ID NO: 5272, and thus concludes that the claims are anticipated. However, whatever else GenBank Accession Number AP000604 teaches, it does not disclose SEQ ID NO: 5272 or the complement thereof. Absent a teaching of each and every element of the claims, including the nucleotide sequence of SEQ ID NO: 5272 or the complement thereof, GenBank Accession Number AP000604 cannot anticipate the claims as

amended.

The Applicants remind the Examiner that during examination, the “claims must be given their broadest *reasonable* interpretation”, M.P.E.P. § 2111 (emphasis added), and this interpretation must be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). One of ordinary skill in the art would not reasonably interpret a sequence complementary to SEQ ID NO: 5272 at merely a particular segment of SEQ ID NO: 5272, as identical to, for example, SEQ ID NO: 5272 or its complement, both of which are 3941 bases in length. Therefore, the Applicants respectfully submit that GenBank Accession Number AP000604 does not anticipate the sequences of the instant claims as amended. Applicants respectfully request reconsideration and withdrawal of this rejection. However, Applicants also submit that the rejection is moot in light of the amendments to the claims.

Claims 2, 6 to 8, and 12 to 14 were also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brennan (U.S. Pat. No. 5,474,796). Office Action at page 22. The Applicants respectfully traverse this rejection.

Once again, the Examiner has applied an untenable interpretation of the claims. One of ordinary skill in the art would not consider a sequence of 10 nucleotides as identical to, for example, SEQ ID NO: 5272, or its complement, both of which are 3941 bases in length. Such an interpretation would be unreasonable. Therefore, the Applicants respectfully submit that Brennan does not anticipate any of the sequences claimed in claims 2, 6 to 8, and 12 to 14 and respectfully request reconsideration and withdrawal of this rejection. However, Applicants

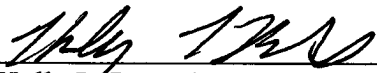
respectfully submit that this rejection is moot as a result of the amendments to the claims.

IV. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5085 if any additional information is necessary for allowance.

Respectfully submitted,

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